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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,013	04/24/2000	HIROYUKI SHIMIZU	32-254P	7526

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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1627

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/530,013

Applicant(s)
Shimizu et al.

Examiner
Ralph Gitomer

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

The preliminary amendment and RCE request received 4/1/02 and the after final amendment received 2/28/02 have been entered and claims 1-6 are currently pending in this application. It is
5 noted no references have been received with the IDS of 4/24/00.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described
in the specification in such a way as to reasonably convey to one
10 skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to include the limitation of
excluding the addition of any degradation-inhibiting agents
which is new matter. A negative limitation requires the highest
15 degree of written description and no written description is found for the new limitation.

The following is a quotation of 35 U.S.C. 103(a) which forms
20 the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be
25 negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered
5 therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the
10 examiner to consider the applicability of 35 U.S.C. 103(c) and
potential 35 U.S.C. 102(f) or (g) prior art under 35
U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lindberg in view of Clerico.

Lindberg (Pharmacology & Tox) entitled ~~✕~~Adsorption of Atrial
15 Natriuretic Peptide to Different Materials~~✕~~ teaches on page 278
column 2 first paragraph, loss of recovery of ANP at different
concentrations in different containers was determined where the
containers include siliconized glass and coated polymers.

The claims differ from Lindberg in that they are directed to
20 a method for inhibiting degradation of the peptides and Lindberg
is directed not to storage but to contacting containers only as
related to concentration.

Clerico (Clin Chem) entitled ~~✖~~Analytical Performance and Clinical Usefulness of a Commercially Available IRMA Kit for Measuring Atrial Natriuretic Peptide in Patients With Heart Failure~~✖~~ teaches on page 1631 column 2 last paragraph, storage of ANP degrades it.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the containers of Lindberg which show the greatest recovery of ANP to store ANP containing specimens as shown by Clerico because Clerico teaches storing ANP in general degrades it. It would appear from Lindberg the silicone coated containers do not degrade ANP as much as others and would therefor desirable for storage of ANP which is known to be sensitive to degradation in storage.

Applicant's arguments filed 4/1/02 have been fully considered but they are not persuasive.

Applicants argue that Lindberg and Clerico do not disclose a method for inhibiting the activation of a substance degrading natriuretic peptides using specialized containers. There is no motivation to combine the references. And the references require degradation inhibiting agents such as aprotinin or HAS.

It is the examiner's position that both Lindberg and Clerico employ containers for holding ANP that are made of the same materials disclosed in the present specification. They would not use containers that would not work, and they show that the

containers that they do use, do work. Regarding the addition of degradation inhibiting agents, on page 4 fifth paragraph of the present specification, aprotinin is known to be added to specimens to inhibit degradation of the peptides. The examples in the specification do not teach the specific addition of such inhibitors but compare the materials of the storage container. This is logical in that the fewer factors measured would lead to the most valuable result. However, it would appear the addition of aprotinin, as is current standard practice, would indeed

inhibit the degradation as the claims are drawn to. The addition of known inhibitors would have the expected result and conversely, the lack of addition of the inhibitors would have the expected result as well. No invention is seen in not adding the known inhibitors. Importantly, no amount of inhibiting is claimed and the claims as presented are written in open-ended ~~comprising~~ terminology which does not exclude additional steps or reagents.

The motivation to modify a reference can come from the knowledge of those skilled in the art, from the prior art reference itself, or from the nature of the problem to be solved. See *In re Rouffet*, 149 F.3d 1350, 1358, 47 USPQ2D (BNA) 1453, 1458 (Fed Cir. 1998)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

5 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status

10 of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business

15 Center for more information.

Ralph Gitomer

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